(a) *Emergency plan.* The hospital must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The hospital must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The hospital must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

* * * * *

(d) *Training and testing.* The hospital must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) * * *

(ii) Provide emergency preparedness training at least every 2 years.

* * * * *

(v) If the emergency preparedness policies and procedures are significantly updated, the hospital must conduct training on the updated policies and procedures.

(2) *Testing.* The hospital must conduct exercises to test the emergency plan at least twice per year. The hospital must do all of the following:

(i) Participate in an annual full-scale exercise that is community-based; or

(A) When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise; or.

(B) If the hospital experiences an actual natural or man-made emergency that requires activation of the emergency plan, the hospital is exempt from engaging in its next required full-scale community-based exercise or individual, facility-based functional exercise following the onset of the emergency event.

(ii) Conduct an additional annual exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the hospital's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the hospital's emergency plan, as needed.

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Subpart C—Basic Hospital Functions

§ 482.21 Condition of participation: Quality assessment and performance improvement program.

The hospital must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.

(a) *Standard: Program scope.* (1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will

improve health outcomes and identify and reduce medical errors.

(2) The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service and operations.

(b) *Standard: Program data.* (1) The program must incorporate quality indicator data including patient care data, and other relevant data, for example, information submitted to, or received from, the hospital's Quality Improvement Organization.

(2) The hospital must use the data collected to—

(i) Monitor the effectiveness and safety of services and quality of care; and

(ii) Identify opportunities for improvement and changes that will lead to improvement.

(3) The frequency and detail of data collection must be specified by the hospital's governing body.

(c) *Standard: Program activities.* (1) The hospital must set priorities for its performance improvement activities that—

(i) Focus on high-risk, high-volume, or problem-prone areas;

(ii) Consider the incidence, prevalence, and severity of problems in those areas; and

(iii) Affect health outcomes, patient safety, and quality of care.

(2) Performance improvement activities must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital.

(3) The hospital must take actions aimed at performance improvement and, after implementing those actions, the hospital must measure its success, and track performance to ensure that improvements are sustained.

(d) *Standard: Performance improvement projects.* As part of its quality assessment and performance improvement program, the hospital must conduct performance improvement projects.

(1) The number and scope of distinct improvement projects conducted annually must be proportional to the scope and complexity of the hospital's services and operations.

(2) A hospital may, as one of its projects, develop and implement an information technology system explicitly designed to improve patient safety and quality of care. This project, in its initial stage of development, does not need to demonstrate measurable improvement in indicators related to health outcomes.

(3) The hospital must document what quality improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

(4) A hospital is not required to participate in a QIO cooperative project, but its own projects are required to be of comparable effort.

(e) *Standard: Executive responsibilities.* The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:

(1) That an ongoing program for quality improvement and patient safety, including the reduction of medical errors, is defined, implemented, and maintained.

(2) That the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety; and that all improvement actions are evaluated.

(3) That clear expectations for safety are established.

(4) That adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's performance and reducing risk to patients.

(5) That the determination of the number of distinct improvement projects is conducted annually.

[68 FR 3454, Jan. 24, 2003]

EFFECTIVE DATE NOTE: At 84 FR 51818, Sept. 30, 2019, §482.21 was amended by revising paragraph (b)(1) and adding paragraph (f), effective Nov. 29, 2019. For the convenience of the user, the added and revised text is set forth as follows:

§ 482.21 Condition of participation: Quality assessment and performance improvement program.

* * * * *

(b) * * *

(1) The program must incorporate quality indicator data including patient care data, and other relevant data such as data submitted to or received from Medicare quality reporting and quality performance programs, including but not limited to data related to hospital readmissions and hospital-acquired conditions.

* * * * *

(f) *Standard: Unified and integrated QAPI program for multi-hospital systems.* If a hospital is part of a hospital system consisting of multiple separately certified hospitals using a system governing body that is legally responsible for the conduct of two or more hospitals, the system governing body can elect to have a unified and integrated QAPI program for all of its member hospitals after determining that such a decision is in accordance with all applicable State and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified hospitals meets all of the requirements of this section. Each separately certified hospital subject to the system governing body must demonstrate that:

(1) The unified and integrated QAPI program is established in a manner that takes into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital; and

(2) The unified and integrated QAPI program establishes and implements policies and procedures to ensure that the needs and concerns of each of its separately certified hospitals, regardless of practice or location, are given due consideration, and that the unified and integrated QAPI program has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed.

§ 482.22 Condition of participation: Medical staff.

The hospital must have an organized medical staff that operates under bylaws approved by the governing body, and which is responsible for the quality of medical care provided to patients by the hospital.

(a) *Standard: Eligibility and process for appointment to medical staff.* The medical staff must be composed of doctors of medicine or osteopathy. In accordance with State law, including scope-of-practice laws, the medical staff may also include other categories of physicians (as listed at § 482.12(c)(1)) and non-physician practitioners who are determined to be eligible for appointment by the governing body.

(1) The medical staff must periodically conduct appraisals of its members.

(2) The medical staff must examine the credentials of all eligible candidates for medical staff membership and make recommendations to the governing body on the appointment of these candidates in accordance with State law, including scope-of-practice laws, and the medical staff bylaws, rules, and regulations. A candidate who has been recommended by the medical staff and who has been appointed by the governing body is subject to all medical staff bylaws, rules, and regulations, in addition to the requirements contained in this section.

(3) When telemedicine services are furnished to the hospital's patients through an agreement with a distant-site hospital, the governing body of the hospital whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (a)(2) of this section, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site hospital when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the hospital's governing body ensures, through its written agreement with the distant-site hospital, that all of the following provisions are met:

(i) The distant-site hospital providing the telemedicine services is a Medicare-participating hospital.

(ii) The individual distant-site physician or practitioner is privileged at the distant-site hospital providing the telemedicine services, which provides a current list of the distant-site physician's or practitioner's privileges at the distant-site hospital.

(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the hospital whose patients are

receiving the telemedicine services is located.

(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the hospital whose patients are receiving the telemedicine services, the hospital has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site hospital such performance information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the hospital's patients and all complaints the hospital has received about the distant-site physician or practitioner.

(4) When telemedicine services are furnished to the hospital's patients through an agreement with a distant-site telemedicine entity, the governing body of the hospital whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (a)(2) of this section, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site telemedicine entity when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the hospital's governing body ensures, through its written agreement with the distant-site telemedicine entity, that the distant-site telemedicine entity furnishes services that, in accordance with § 482.12(e), permit the hospital to comply with all applicable conditions of participation for the contracted services. The hospital's governing body must also ensure, through its written agreement with the distant-site telemedicine entity, that all of the following provisions are met:

(i) The distant-site telemedicine entity's medical staff credentialing and privileging process and standards at least meet the standards at § 482.12(a)(1) through (a)(7) and § 482.22(a)(1) through (a)(2).

(ii) The individual distant-site physician or practitioner is privileged at the distant-site telemedicine entity providing the telemedicine services, which provides the hospital with a current list of the distant-site physician's or practitioner's privileges at the distant-site telemedicine entity.

(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the hospital whose patients are receiving such telemedicine services is located.

(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the hospital whose patients are receiving the telemedicine services, the hospital has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site telemedicine entity such performance information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the hospital's patients, and all complaints the hospital has received about the distant-site physician or practitioner.

(b) *Standard: Medical staff organization and accountability.* The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to patients.

(1) The medical staff must be organized in a manner approved by the governing body.

(2) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.

(3) The responsibility for organization and conduct of the medical staff must be assigned only to one of the following:

(i) An individual doctor of medicine or osteopathy.

(ii) A doctor of dental surgery or dental medicine, when permitted by State law of the State in which the hospital is located.

(iii) A doctor of podiatric medicine, when permitted by State law of the State in which the hospital is located.

(4) If a hospital is part of a hospital system consisting of multiple separately certified hospitals and the system elects to have a unified and integrated medical staff for its member hospitals, after determining that such a decision is in accordance with all applicable State and local laws, each separately certified hospital must demonstrate that:

(i) The medical staff members of each separately certified hospital in the system (that is, all medical staff members who hold specific privileges to practice at that hospital) have voted by majority, in accordance with medical staff bylaws, either to accept a unified and integrated medical staff structure or to opt out of such a structure and to maintain a separate and distinct medical staff for their respective hospital;

(ii) The unified and integrated medical staff has bylaws, rules, and requirements that describe its processes for self-governance, appointment, credentialing, privileging, and oversight, as well as its peer review policies and due process rights guarantees, and which include a process for the members of the medical staff of each separately certified hospital (that is, all medical staff members who hold specific privileges to practice at that hospital) to be advised of their rights to opt out of the unified and integrated medical staff structure after a majority vote by the members to maintain a separate and distinct medical staff for their hospital;

(iii) The unified and integrated medical staff is established in a manner that takes into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital; and

(iv) The unified and integrated medical staff establishes and implements policies and procedures to ensure that the needs and concerns expressed by members of the medical staff, at each of its separately certified hospitals, regardless of practice or location, are given due consideration, and that the unified and integrated medical staff has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed.

(c) *Standard: Medical staff bylaws.* The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must:

(1) Be approved by the governing body.

(2) Include a statement of the duties and privileges of each category of medical staff (e.g., active, courtesy, etc.)

(3) Describe the organization of the medical staff.

(4) Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body.

(5) Include a requirement that—

(i) A medical history and physical examination be completed and documented for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

(ii) An updated examination of the patient, including any changes in the patient's condition, be completed and documented within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before admission or registration. The updated examination of the patient, including any changes in the patient's condition, must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

(6) Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges. For distant-site physicians and practitioners requesting privileges to furnish telemedicine services under an agreement with the hospital, the criteria for determining

privileges and the procedure for applying the criteria are also subject to the requirements in § 482.12(a)(8) and (a)(9), and § 482.22(a)(3) and (a)(4).

(d) *Standard: Autopsies.* The medical staff should attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. The mechanism for documenting permission to perform an autopsy must be defined. There must be a system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed.

[51 FR 22042, June 17, 1986, as amended at 59 FR 64152, Dec. 13, 1994; 71 FR 68694, Nov. 27, 2006; 72 FR 66933, Nov. 27, 2007; 76 FR 25563, May 5, 2011; 77 FR 29074, May 16, 2012; 79 FR 27154, May 12, 2014]

EFFECTIVE DATE NOTE: At 84 FR 51818, Sept. 30, 2019, § 482.22 was amended by revising paragraphs (c)(5)(i) and (ii); adding paragraphs (c)(5)(iii), (iv), and (v); and removing paragraph (d), effective Nov. 29, 2019. For the convenience of the user, the added and revised text is set forth as follows:

§ 482.22 Condition of participation: Medical staff.

* * * * *

(c) * * *

(5) * * *

(i) A medical history and physical examination be completed and documented for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, and except as provided under paragraph (c)(5)(iii) of this section. The medical history and physical examination must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oral and maxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

(ii) An updated examination of the patient, including any changes in the patient's condition, be completed and documented within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before admission or registration, and except as provided under paragraph (c)(5)(iii) of this section. The updated examination of the patient, including any changes in the patient's condition, must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oral and maxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

(iii) An assessment of the patient (in lieu of the requirements of paragraphs (c)(5)(i) and (ii) of this section) be completed and documented after registration, but prior to surgery or a procedure requiring anesthesia services, when the patient is receiving specific outpatient surgical or procedural services and when the medical staff has chosen to develop and maintain a policy that identifies, in accordance with the requirements at paragraph (c)(5)(v) of this section, specific patients as not requiring a comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services. The assessment must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oral and maxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

(iv) The medical staff develop and maintain a policy that identifies those patients for whom the assessment requirements of paragraph (c)(5)(iii) of this section would apply. The provisions of paragraphs (c)(5)(iii), (iv), and (v) of this section do not apply to a medical staff that chooses to maintain a policy that adheres to the requirements of paragraphs of (c)(5)(i) and (ii) of this section for all patients.

(v) The medical staff, if it chooses to develop and maintain a policy for the identification of specific patients to whom the assessment requirements in paragraph (c)(5)(iii) of this section would apply, must demonstrate evidence that the policy applies only to those patients receiving specific outpatient surgical or procedural services as well as evidence that the policy is based on:

(A) Patient age, diagnoses, the type and number of surgeries and procedures scheduled to be performed, comorbidities, and the level of anesthesia required for the surgery or procedure.

(B) Nationally recognized guidelines and standards of practice for assessment of specific types of patients prior to specific outpatient surgeries and procedures.

(C) Applicable state and local health and safety laws.

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§ 482.23 Condition of participation: Nursing services.

The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse.

(a) *Standard: Organization.* The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.

(b) *Standard: Staffing and delivery of care.* The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.

(1) The hospital must provide 24-hour nursing services furnished or supervised by a registered nurse, and have a licensed practical nurse or registered nurse on duty at all times, except for rural hospitals that have in effect a 24-hour nursing waiver granted under §488.54(c) of this chapter.

(2) The nursing service must have a procedure to ensure that hospital nursing personnel for whom licensure is required have valid and current licensure.

(3) A registered nurse must supervise and evaluate the nursing care for each patient.

(4) The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient. The nursing care plan may be part of an interdisciplinary care plan.

(5) A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available.

(6) Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing service.

(c) *Standard: Preparation and administration of drugs.* (1) Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under §482.12(c), and accepted standards of practice.

(i) Drugs and biologicals may be prepared and administered on the orders of other practitioners not specified under §482.12(c) only if such practitioners are acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

(ii) Drugs and biologicals may be prepared and administered on the orders contained within pre-printed and electronic standing orders, order sets, and protocols for patient orders only if such orders meet the requirements of §482.24(c)(3).

(2) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

(3) With the exception of influenza and pneumococcal vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders in accordance with State law and hospital policy, and who is responsible for the care of the patient as specified under §482.12(c).

(i) If verbal orders are used, they are to be used infrequently.

(ii) When verbal orders are used, they must only be accepted by persons who are authorized to do so by hospital policy and procedures consistent with Federal and State law.

(iii) Orders for drugs and biologicals may be documented and signed by other practitioners not specified under §482.12(c) only if such practitioners are acting in accordance with State law,

including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

(4) Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures.

(5) There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

(6) The hospital may allow a patient (or his or her caregiver/support person where appropriate) to self-administer both hospital-issued medications and the patient's own medications brought into the hospital, as defined and specified in the hospital's policies and procedures.

(i) If the hospital allows a patient to self-administer specific hospital-issued medications, then the hospital must have policies and procedures in place to:

(A) Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration.

(B) Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s).

(C) Instruct the patient (or the patient's caregiver/support person where appropriate) in the safe and accurate administration of the specified medication(s).

(D) Address the security of the medication(s) for each patient.

(E) Document the administration of each medication, as reported by the patient (or the patient's caregiver/support person where appropriate), in the patient's medical record.

(ii) If the hospital allows a patient to self-administer his or her own specific medications brought into the hospital, then the hospital must have policies and procedures in place to:

(A) Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration of medications the patient brought into the hospital.

(B) Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s), and also determine if the patient (or the patient's caregiver/support person where appropriate) needs instruction in the safe and accurate administration of the specified medication(s).

(C) Identify the specified medication(s) and visually evaluate the medication(s) for integrity.

(D) Address the security of the medication(s) for each patient.

(E) Document the administration of each medication, as reported by the patient (or the patient's caregiver/support person where appropriate), in the patient's medical record.

[51 FR 22042, June 17, 1986, as amended at 67 FR 61814, Oct. 2, 2002; 71 FR 68694, Nov. 27, 2006; 72 FR 66933, Nov. 27, 2007; 77 FR 29074, May 16, 2012; 78 FR 50970, Aug. 19, 2013; 79 FR 44129, July 30, 2014]

EFFECTIVE DATE NOTE: At 84 FR 51819, Sept. 30, 2019, §482.23 was amended by revising paragraphs (b) introductory text and (b)(4) and (6); adding paragraph (b)(7); and revising (c)(1) introductory text and (c)(3), effective Nov. 29, 2019. For the convenience of the user, the added and revised text is set forth as follows:

§482.23 Condition of participation: Nursing services.

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(b) *Standard: Staffing and delivery of care.* The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for the care of any patient.

* * * * *

(4) The hospital must ensure that the nursing staff develops and keeps current a nursing care plan for each patient that reflects the patient's goals and the nursing care to be provided to meet the patient's needs. The nursing care plan may be part of an interdisciplinary care plan.

* * * * *

(6) All licensed nurses who provide services in the hospital must adhere to the policies and procedures of the hospital. The director

of nursing service must provide for the adequate supervision and evaluation of the clinical activities of all nursing personnel which occur within the responsibility of the nursing service, regardless of the mechanism through which those personnel are providing services (that is, hospital employee, contract, lease, other agreement, or volunteer).

(7) The hospital must have policies and procedures in place establishing which outpatient departments, if any, are not required under hospital policy to have a registered nurse present. The policies and procedures must:

(i) Establish the criteria such outpatient departments must meet, taking into account the types of services delivered, the general level of acuity of patients served by the department, and the established standards of practice for the services delivered;

(ii) Establish alternative staffing plans;

(iii) Be approved by the director of nursing;

(iv) Be reviewed at least once every 3 years.

(c) * * *

(1) Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care, and accepted standards of practice.

* * * * *

(3) With the exception of influenza and pneumococcal vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders in accordance with State law and hospital policy, and who is responsible for the care of the patient.

(i) If verbal orders are used, they are to be used infrequently.

(ii) When verbal orders are used, they must only be accepted by persons who are authorized to do so by hospital policy and procedures consistent with Federal and State law.

(iii) Orders for drugs and biologicals may be documented and signed by other practitioners only if such practitioners are acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

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§ 482.24 Condition of participation: Medical record services.

The hospital must have a medical record service that has administrative responsibility for medical records. A medical record must be maintained for every individual evaluated or treated in the hospital.

(a) *Standard: Organization and staffing.* The organization of the medical record service must be appropriate to the scope and complexity of the services performed. The hospital must employ adequate personnel to ensure prompt completion, filing, and retrieval of records.

(b) *Standard: Form and retention of record.* The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentification and protects the security of all record entries.

(1) Medical records must be retained in their original or legally reproduced form for a period of at least 5 years.

(2) The hospital must have a system of coding and indexing medical records. The system must allow for timely retrieval by diagnosis and procedure, in order to support medical care evaluation studies.

(3) The hospital must have a procedure for ensuring the confidentiality of patient records. In-formation from or copies of records may be released only to authorized individuals, and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records must be released by the hospital only in accordance with Federal or State laws, court orders, or subpoenas.

(c) *Standard: Content of record.* The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services.

(1) All patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures.

(2) All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner or by another practitioner who

is responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

(3) Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders only if the hospital:

(i) Establishes that such orders and protocols have been reviewed and approved by the medical staff and the hospital's nursing and pharmacy leadership;

(ii) Demonstrates that such orders and protocols are consistent with nationally recognized and evidence-based guidelines;

(iii) Ensures that the periodic and regular review of such orders and protocols is conducted by the medical staff and the hospital's nursing and pharmacy leadership to determine the continuing usefulness and safety of the orders and protocols; and

(iv) Ensures that such orders and protocols are dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or by another practitioner responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

(4) All records must document the following, as appropriate:

(i) Evidence of—

(A) A medical history and physical examination completed and documented no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.

(B) An updated examination of the patient, including any changes in the patient's condition, when the medical history and physical examination are completed within 30 days before admission or registration. Documentation of the updated examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.

(ii) Admitting diagnosis.

(iii) Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient.

(iv) Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia.

(v) Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.

(vi) All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.

(vii) Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow-up care.

(viii) Final diagnosis with completion of medical records within 30 days following discharge.

[51 FR 22042, June 17, 1986, as amended at 71 FR 68694, Nov. 27, 2006; 72 FR 66933, Nov. 27, 2007; 77 FR 29074, May 16, 2012]

EFFECTIVE DATE NOTE: At 84 FR 51819, Sept. 30, 2019, §482.24 was amended by revising paragraphs (c)(4)(i)(A) and (B), and adding paragraph (c)(4)(i)(C), effective Nov. 29, 2019. For the convenience of the user, the added and revised text is set forth as follows:

§482.24 Condition of participation: Medical record services.

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(c) * * *

(4) * * *

(i) * * *

(A) A medical history and physical examination completed and documented no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, and except as provided under paragraph (c)(4)(i)(C) of this section. The medical history and physical examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.

(B) An updated examination of the patient, including any changes in the patient's condition, when the medical history and physical examination are completed within 30 days before admission or registration, and except as provided under paragraph (c)(4)(i)(C) of this section. Documentation of the updated examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.

(C) An assessment of the patient (in lieu of the requirements of paragraphs (c)(4)(i)(A) and (B) of this section) completed and documented after registration, but prior to surgery or a procedure requiring anesthesia services, when the patient is receiving specific outpatient surgical or procedural services and when the medical staff has chosen to develop and maintain a policy that identifies, in accordance with the requirements at §482.22(c)(5)(v), specific patients as not requiring a comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services.

* * * * *

§ 482.25 Condition of participation: Pharmaceutical services.

The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.

(a) *Standard: Pharmacy management and administration.* The pharmacy or drug storage area must be administered in accordance with accepted professional principles.

(1) A full-time, part-time, or consulting pharmacist must be responsible for developing, supervising, and coordinating all the activities of the pharmacy services.

(2) The pharmaceutical service must have an adequate number of personnel to ensure quality pharmaceutical services, including emergency services.

(3) Current and accurate records must be kept of the receipt and disposition of all scheduled drugs.

(b) *Standard: Delivery of services.* In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.

(1) All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws.

(2)(i) All drugs and biologicals must be kept in a secure area, and locked when appropriate.

(ii) Drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area.

(iii) Only authorized personnel may have access to locked areas.

(3) Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.

(4) When a pharmacist is not available, drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and State law.

(5) Drugs and biologicals not specifically prescribed as to time or number of doses must automatically be stopped after a reasonable time that is predetermined by the medical staff.

(6) Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the hospital's quality assessment and performance improvement program.

(7) Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

(8) Information relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration must be available to the professional staff.

(9) A formulary system must be established by the medical staff to assure quality pharmaceuticals at reasonable costs.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986; 71 FR 68694, Nov. 27, 2006; 77 FR 29075, May 16, 2012]

§ 482.26 Condition of participation: Radiologic services.

The hospital must maintain, or have available, diagnostic radiologic services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.

(a) *Standard: Radiologic services.* The hospital must maintain, or have available, radiologic services according to needs of the patients.

(b) *Standard: Safety for patients and personnel.* The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.

(1) Proper safety precutions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.

(2) Periodic inspection of equipment must be made and hazards identified must be promptly corrected.

(3) Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.

(4) Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services.

(c) *Standard: Personnel.* (1) A qualified full-time, part-time, or consulting radiologist must supervise the ionizing radiology services and must interpret only those radiologic tests that are determined by the medical staff to require a radiologist's specialized knowledge. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.

(2) Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.

(d) *Standard: Records.* Records of radiologic services must be maintained.

(1) The radiologist or other practitioner who performs radiology services must sign reports of his or her interpretations.

(2) The hospital must maintain the following for at least 5 years:

(i) Copies of reports and printouts.

(ii) Films, scans, and other image records, as appropriate.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]

§ 482.27 Condition of participation: Laboratory services.

The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients. The hospital must ensure that all laboratory services provided to its patients are performed in a facility certified in accordance with part 493 of this chapter.

(a) *Standard: Adequacy of laboratory services.* The hospital must have laboratory services available, either directly or through a contractual agreement with a certified laboratory that meets requirements of part 493 of this chapter.

(1) Emergency laboratory services must be available 24 hours a day.

(2) A written description of services provided must be available to the medical staff.

(3) The laboratory must make provision for proper receipt and reporting of tissue specimens.

(4) The medical staff and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.

(b) *Standard: Potentially infectious blood and blood components*—(1) *Potentially human immunodeficiency virus (HIV) infectious blood and blood components.* Potentially HIV infectious blood and blood components are prior collections from a donor—

(i) Who tested negative at the time of donation but tests reactive for evidence of HIV infection on a later donation;

(ii) Who tests positive on the supplemental (additional, more specific) test or other follow-up testing required by FDA; and

(iii) For whom the timing of seroconversion cannot be precisely estimated.

(2) *Potentially hepatitis C virus (HCV) infectious blood and blood components.*

Potentially HCV infectious blood and blood components are the blood and blood components identified in 21 CFR 610.47.

(3) *Services furnished by an outside blood collecting establishment.* If a hospital regularly uses the services of an outside blood collecting establishment, it must have an agreement with the blood collecting establishment that governs the procurement, transfer, and availability of blood and blood components. The agreement must require that the blood collecting establishment notify the hospital—

(i) Within 3 calendar days if the blood collecting establishment supplied blood and blood components collected from a donor who tested negative at the time of donation but tests reactive for evidence of HIV or HCV infection on a later donation or who is determined to be at increased risk for transmitting HIV or HCV infection;

(ii) Within 45 days of the test, of the results of the supplemental (additional, more specific) test for HIV or HCV, as relevant, or other follow-up testing required by FDA; and

(iii) Within 3 calendar days after the blood collecting establishment supplied blood and blood components collected from an infectious donor, whenever records are available, as set forth at 21 CFR 610.48(b)(3).

(4) *Quarantine and disposition of blood and blood components pending completion of testing.* If the blood collecting establishment (either internal or under an agreement) notifies the hospital of the reactive HIV or HCV screening test results, the hospital must determine the disposition of the blood or blood product and quarantine all blood and blood components from previous donations in inventory.

(i) If the blood collecting establishment notifies the hospital that the result of the supplemental (additional, more specific) test or other follow-up testing required by FDA is negative, absent other informative test results, the hospital may release the blood and blood components from quarantine.

(ii) If the blood collecting establishment notifies the hospital that the result of the supplemental, (additional, more specific) test or other follow-up testing required by FDA is positive, the hospital must—

(A) Dispose of the blood and blood components; and

(B) Notify the transfusion beneficiaries as set forth in paragraph (b)(6) of this section.

(iii) If the blood collecting establishment notifies the hospital that the result of the supplemental, (additional, more specific) test or other follow-up testing required by FDA is indeterminate, the hospital must destroy or label prior collections of blood or blood components held in quarantine as set forth at 21 CFR 610.46(b)(2), 610.47(b)(2), and 610.48(c)(2).

(5) *Recordkeeping by the hospital.* The hospital must maintain—

(i) Records of the source and disposition of all units of blood and blood components for at least 10 years from the date of disposition in a manner that permits prompt retrieval; and

(ii) A fully funded plan to transfer these records to another hospital or other entity if such hospital ceases operation for any reason.

(6) *Patient notification.* If the hospital has administered potentially HIV or HCV infectious blood or blood components (either directly through its own blood collecting establishment or under an agreement) or released such blood or blood components to another entity or individual, the hospital must take the following actions:

(i) Make reasonable attempts to notify the patient, or to notify the attending physician or the physician who ordered the blood or blood component and ask the physician to notify the patient, or other individual as permitted under paragraph (b)(10) of this section, that potentially HIV or HCV infectious blood or blood components were transfused to the patient and that there may be a need for HIV or HCV testing and counseling.

(ii) If the physician is unavailable or declines to make the notification, make reasonable attempts to give this notification to the patient, legal guardian, or relative.

(iii) Document in the patient's medical record the notification or attempts to give the required notification.

(7) *Timeframe for notification*—(i) *For donors tested on or after February 20,*

2008. For notifications resulting from donors tested on or after February 20, 2008 as set forth at 21 CFR 610.46 and 21 CFR 610.47 the notification effort begins when the blood collecting establishment notifies the hospital that it received potentially HIV or HCV infectious blood and blood components. The hospital must make reasonable attempts to give notification over a period of 12 weeks unless—

(A) The patient is located and notified; or

(B) The hospital is unable to locate the patient and documents in the patient's medical record the extenuating circumstances beyond the hospital's control that caused the notification timeframe to exceed 12 weeks.

(ii) For donors tested before February 20, 2008. For notifications resulting from donors tested before February 20, 2008 as set forth at 21 CFR 610.48(b) and (c), the notification effort begins when the blood collecting establishment notifies the hospital that it received potentially HCV infectious blood and blood components. The hospital must make reasonable attempts to give notification and must complete the actions within 1 year of the date on which the hospital received notification from the outside blood collecting establishment.

(8) *Content of notification*. The notification must include the following information:

(i) A basic explanation of the need for HIV or HCV testing and counseling;

(ii) Enough oral or written information so that an informed decision can be made about whether to obtain HIV or HCV testing and counseling; and

(iii) A list of programs or places where the person can obtain HIV or HCV testing and counseling, including any requirements or restrictions the program may impose.

(9) *Policies and procedures*. The hospital must establish policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for the confidentiality of medical records and other patient information.

(10) *Notification to legal representative or relative*. If the patient has been adjudged incompetent by a State court, the physician or hospital must notify a legal representative designated in accordance with State law. If the patient is competent, but State law permits a legal representative or relative to receive the information on the patient's behalf, the physician or hospital must notify the patient or his or her legal representative or relative. For possible HIV infectious transfusion beneficiaries that are deceased, the physician or hospital must inform the deceased patient's legal representative or relative. If the patient is a minor, the parents or legal guardian must be notified.

(11) *Applicability*. HCV notification requirements resulting from donors tested before February 20, 2008 as set forth at 21 CFR 610.48 will expire on August 24, 2015.

(c) *General blood safety issues*. For lookback activities only related to new blood safety issues that are identified after August 24, 2007, hospitals must comply with FDA regulations as they pertain to blood safety issues in the following areas:

(1) Appropriate testing and quarantining of infectious blood and blood components.

(2) Notification and counseling of beneficiaries that may have received infectious blood and blood components.

[57 FR 7136, Feb. 28, 1992, as amended at 61 FR 47433, Sept. 9, 1996; 72 FR 48573, Aug. 24, 2007]

EFFECTIVE DATE NOTE: At 84 FR 51819, Sept. 30, 2019, §482.27 was amended by revising paragraph (b)(7) and removing paragraph (b)(11), effective Nov. 29, 2019. For the convenience of the user, the revised text is set forth as follows:

§482.27 Condition of participation: Laboratory services.

* * * * *

(b) * * *

(7) *Timeframe for notification*— For donors tested on or after February 20, 2008. For notifications resulting from donors tested on or after February 20, 2008 as set forth at 21 CFR 610.46 and 610.47 the notification effort begins when the blood collecting establishment notifies the hospital that it received potentially HIV or HCV infectious blood and blood components. The hospital must make reasonable attempts to give notification over a period of 12 weeks unless—

(i) The patient is located and notified; or

(ii) The hospital is unable to locate the patient and documents in the patient's medical record the extenuating circumstances beyond the hospital's control that caused the notification timeframe to exceed 12 weeks.

* * * * *

§ 482.28 Condition of participation: Food and dietetic services.

The hospital must have organized dietary services that are directed and staffed by adequate qualified personnel. However, a hospital that has a contract with an outside food management company may be found to meet this Condition of participation if the company has a dietitian who serves the hospital on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standards specified in this section and provides for constant liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment.

(a) *Standard: Organization.* (1) The hospital must have a full-time employee who—

(i) Serves as director of the food and dietetic service;

(ii) Is responsible for the daily management of the dietary services; and

(iii) Is qualified by experience or training.

(2) There must be a qualified dietitian, full-time, part-time, or on a consultant basis.

(3) There must be administrative and technical personnel competent in their respective duties.

(b) *Standard: Diets.* Menus must meet the needs of the patients.

(1) Individual patient nutritional needs must be met in accordance with recognized dietary practices.

(2) All patient diets, including therapeutic diets, must be ordered by a practitioner responsible for the care of the patient, or by a qualified dietitian or qualified nutrition professional as authorized by the medical staff and in accordance with State law governing dietitians and nutrition professionals.

(3) A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.

[51 FR 22042, June 17, 1986, as amended at 79 FR 27154, May 12, 2014]

§ 482.30 Condition of participation: Utilization review.

The hospital must have in effect a utilization review (UR) plan that provides for review of services furnished by the institution and by members of the medical staff to patients entitled to benefits under the Medicare and Medicaid programs.

(a) *Applicability.* The provisions of this section apply except in either of the following circumstances:

(1) A Utilization and Quality Control Quality Improvement Organization (QIO) has assumed binding review for the hospital.

(2) CMS has determined that the UR procedures established by the State under title XIX of the Act are superior to the procedures required in this section, and has required hospitals in that State to meet the UR plan requirements under §§ 456.50 through 456.245 of this chapter.

(b) *Standard: Composition of utilization review committee.* A UR committee consisting of two or more practitioners must carry out the UR function. At least two of the members of the committee must be doctors of medicine or osteopathy. The other members may be any of the other types of practitioners specified in § 482.12(c)(1).

(1) Except as specified in paragraphs (b) (2) and (3) of this section, the UR committee must be one of the following:

(i) A staff committee of the institution;

(ii) A group outside the institution—

(A) Established by the local medical society and some or all of the hospitals in the locality; or

(B) Established in a manner approved by CMS.

(2) If, because of the small size of the institution, it is impracticable to have a properly functioning staff committee, the UR committee must be established as specified in paragraph (b)(1)(ii) of this section.

(3) The committee's or group's reviews may not be conducted by any individual who—

(i) Has a direct financial interest (for example, an ownership interest) in that hospital; or

(ii) Was professionally involved in the care of the patient whose case is being reviewed.

(c) *Standard: Scope and frequency of review.* (1) The UR plan must provide for review for Medicare and Medicaid patients with respect to the medical necessity of—

(i) Admissions to the institution;

(ii) The duration of stays; and

(iii) Professional services furnished, including drugs and biologicals.

(2) Review of admissions may be performed before, at, or after hospital admission.

(3) Except as specified in paragraph (e) of this section, reviews may be conducted on a sample basis.

(4) Hospitals that are paid for inpatient hospital services under the prospective payment system set forth in part 412 of this chapter must conduct review of duration of stays and review of professional services as follows:

(i) For duration of stays, these hospitals need review only cases that they reasonably assume to be outlier cases based on extended length of stay, as described in § 412.80(a)(1)(i) of this chapter; and

(ii) For professional services, these hospitals need review only cases that they reasonably assume to be outlier cases based on extraordinarily high costs, as described in § 412.80(a)(1)(ii) of this chapter.

(d) *Standard: Determination regarding admissions or continued stays.* (1) The determination that an admission or continued stay is not medically necessary—

(i) May be made by one member of the UR committee if the practitioner or practitioners responsible for the care of the patient, as specified of § 482.12(c), concur with the determination or fail to present their views when afforded the opportunity; and

(ii) Must be made by at least two members of the UR committee in all other cases.

(2) Before making a determination that an admission or continued stay is not medically necessary, the UR committee must consult the practitioner or practitioners responsible for the care of the patient, as specified in § 482.12(c), and afford the practitioner or practitioners the opportunity to present their views.

(3) If the committee decides that admission to or continued stay in the hospital is not medically necessary, written notification must be given, no later than 2 days after the determination, to the hospital, the patient, and the practitioner or practitioners responsible for the care of the patient, as specified in § 482.12(c);

(e) *Standard: Extended stay review.* (1) In hospitals that are not paid under the prospective payment system, the UR committee must make a periodic review, as specified in the UR plan, of each current inpatient receiving hospital services during a continuous period of extended duration. The scheduling of the periodic reviews may—

(i) Be the same for all cases; or

(ii) Differ for different classes of cases.

(2) In hospitals paid under the prospective payment system, the UR committee must review all cases reasonably assumed by the hospital to be outlier cases because the extended length of stay exceeds the threshold criteria for the diagnosis, as described in § 412.80(a)(1)(i). The hospital is not required to review an extended stay that does not exceed the outlier threshold for the diagnosis.

(3) The UR committee must make the periodic review no later than 7 days after the day required in the UR plan.

(f) *Standard: Review of professional services.* The committee must review professional services provided, to determine medical necessity and to promote the most efficient use of available health facilities and services.

§ 482.41 Condition of participation: Physical environment.

The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community.

(a) *Standard: Buildings.* The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner

that the safety and well-being of patients are assured.

(1) There must be emergency power and lighting in at least the operating, recovery, intensive care, and emergency rooms, and stairwells. In all other areas not serviced by the emergency supply source, battery lamps and flashlights must be available.

(2) There must be facilities for emergency gas and water supply.

(b) *Standard: Life safety from fire.* (1) Except as otherwise provided in this section—

(i) The hospital must meet the applicable provisions and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4.) Outpatient surgical departments must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served.

(ii) Notwithstanding paragraph (b)(1)(i) of this section, corridor doors and doors to rooms containing flammable or combustible materials must be provided with positive latching hardware. Roller latches are prohibited on such doors.

(2) In consideration of a recommendation by the State survey agency or Accrediting Organization or at the discretion of the Secretary, may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon a hospital, but only if the waiver will not adversely affect the health and safety of the patients.

(3) The provisions of the Life Safety Code do not apply in a State where CMS finds that a fire and safety code imposed by State law adequately protects patients in hospitals.

(4) The hospital must have procedures for the proper routine storage and prompt disposal of trash.

(5) The hospital must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel and guests; evacuation; and cooperation with fire fighting authorities.

(6) The hospital must maintain written evidence of regular inspection and approval by State or local fire control agencies.

(7) A hospital may install alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access;

(8) When a sprinkler system is shut down for more than 10 hours, the hospital must:

(i) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or

(ii) Establish a fire watch until the system is back in service.

(9) Buildings must have an outside window or outside door in every sleeping room, and for any building constructed after July 5, 2016 the sill height must not exceed 36 inches above the floor. Windows in atrium walls are considered outside windows for the purposes of this requirement.

(i) The sill height requirement does not apply to newborn nurseries and rooms intended for occupancy for less than 24 hours.

(ii) The sill height in special nursing care areas of new occupancies must not exceed 60 inches.

(c) *Standard: Building safety.* Except as otherwise provided in this section, the hospital must meet the applicable provisions and must proceed in accordance with the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5 and TIA 12–6).

(1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to a hospital.

(2) If application of the Health Care Facilities Code required under paragraph (c) of this section would result in unreasonable hardship for the hospital, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of patients.

(d) *Standard: Facilities.* The hospital must maintain adequate facilities for its services.

(1) Diagnostic and therapeutic facilities must be located for the safety of patients.

(2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

(3) The extent and complexity of facilities must be determined by the services offered.

(4) There must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.

(e) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the FEDERAL REGISTER to announce the changes.

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, *www.nfpa.org*, 1.617.770.3000.

(i) NFPA 99, Standards for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011.

(ii) TIA 12–2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12–3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12–4 to NFPA 99, issued March 7, 2013.

(v) TIA 12–5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12–6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011;

(viii) TIA 12–1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12–2 to NFPA 101, issued October 30, 2012.

(x) TIA 12–3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12–4 to NFPA 101, issued October 22, 2013.

(2) [Reserved]

[51 FR 22042, June 17, 1986, as amended at 53 FR 11509, Apr. 7, 1988; 68 FR 1386, Jan. 10, 2003; 69 FR 49267, Aug. 11, 2004; 70 FR 15238, Mar. 25, 2005; 71 FR 55340, Sept. 22, 2006; 81 FR 26899, May 4, 2016; 81 FR 42548, June 30, 2016]

§ 482.42 Condition of participation: Infection control.

The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.

(a) *Standard: Organization and policies.* A person or persons must be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases. The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.

(b) *Standard: Responsibilities of chief executive officer, medical staff, and director of nursing services.* The chief executive officer, the medical staff, and the director of nursing services must—

(1) Ensure that the hospital-wide quality assessment and performance improvement (QAPI) program and training programs address problems identified by the infection control officer or officers; and

(2) Be responsible for the implementation of successful corrective action plans in affected problem areas.

[51 FR 22042, June 17, 1986, as amended at 77 FR 29075, May 16, 2012; 79 FR 10396, Feb. 25, 2014]

EFFECTIVE DATE NOTE: At 84 FR 51820, Sept. 30, 2019, § 482.42 was revised, effective Nov. 29, 2019. For the convenience of the user, the revised text is set forth as follows:

§ 482.42 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

The hospital must have active hospital-wide programs for the surveillance, prevention, and control of HAIs and other infectious diseases, and for the optimization of antibiotic use through stewardship. The programs must demonstrate adherence to nationally recognized infection prevention and

control guidelines, as well as to best practices for improving antibiotic use where applicable, and for reducing the development and transmission of HAIs and antibiotic-resistant organisms. Infection prevention and control problems and antibiotic use issues identified in the programs must be addressed in collaboration with the hospital-wide quality assessment and performance improvement (QAPI) program.

(a) *Standard: Infection prevention and control program organization and policies.* The hospital must demonstrate that:

(1) An individual (or individuals), who is qualified through education, training, experience, or certification in infection prevention and control, is appointed by the governing body as the infection preventionist(s)/infection control professional(s) responsible for the infection prevention and control program and that the appointment is based on the recommendations of medical staff leadership and nursing leadership;

(2) The hospital infection prevention and control program, as documented in its policies and procedures, employs methods for preventing and controlling the transmission of infections within the hospital and between the hospital and other institutions and settings;

(3) The infection prevention and control program includes surveillance, prevention, and control of HAIs, including maintaining a clean and sanitary environment to avoid sources and transmission of infection, and addresses any infection control issues identified by public health authorities; and

(4) The infection prevention and control program reflects the scope and complexity of the hospital services provided.

(b) *Standard: Antibiotic stewardship program organization and policies.* The hospital must demonstrate that:

(1) An individual (or individuals), who is qualified through education, training, or experience in infectious diseases and/or antibiotic stewardship, is appointed by the governing body as the leader(s) of the antibiotic stewardship program and that the appointment is based on the recommendations of medical staff leadership and pharmacy leadership;

(2) The hospital-wide antibiotic stewardship program:

(i) Demonstrates coordination among all components of the hospital responsible for antibiotic use and resistance, including, but not limited to, the infection prevention and control program, the QAPI program, the medical staff, nursing services, and pharmacy services;

(ii) Documents the evidence-based use of antibiotics in all departments and services of the hospital; and

(iii) Documents any improvements, including sustained improvements, in proper antibiotic use;

(3) The antibiotic stewardship program adheres to nationally recognized guidelines, as well as best practices, for improving antibiotic use; and

(4) The antibiotic stewardship program reflects the scope and complexity of the hospital services provided.

(c) Standard: Leadership responsibilities. (1) The governing body must ensure all of the following:

(i) Systems are in place and operational for the tracking of all infection surveillance, prevention, and control, and antibiotic use activities, in order to demonstrate the implementation, success, and sustainability of such activities.

(ii) All HAIs and other infectious diseases identified by the infection prevention and control program as well as antibiotic use issues identified by the antibiotic stewardship program are addressed in collaboration with hospital QAPI leadership.

(2) The infection preventionist(s)/infection control professional(s) is responsible for:

(i) The development and implementation of hospital-wide infection surveillance, prevention, and control policies and procedures that adhere to nationally recognized guidelines.

(ii) All documentation, written or electronic, of the infection prevention and control program and its surveillance, prevention, and control activities.

(iii) Communication and collaboration with the hospital's QAPI program on infection prevention and control issues.

(iv) Competency-based training and education of hospital personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the hospital, on the practical applications of infection prevention and control guidelines, policies, and procedures.

(v) The prevention and control of HAIs, including auditing of adherence to infection prevention and control policies and procedures by hospital personnel.

(vi) Communication and collaboration with the antibiotic stewardship program.

(3) The leader(s) of the antibiotic stewardship program is responsible for:

(i) The development and implementation of a hospital-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics.

(ii) All documentation, written or electronic, of antibiotic stewardship program activities.

(iii) Communication and collaboration with medical staff, nursing, and pharmacy leadership, as well as with the hospital's infection prevention and control and QAPI programs, on antibiotic use issues.

(iv) Competency-based training and education of hospital personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the hospital, on the practical applications of antibiotic stewardship guidelines, policies, and procedures.

(d) *Standard: Unified and integrated infection prevention and control and antibiotic stewardship programs for multi-hospital systems.* If a hospital is part of a hospital system consisting of multiple separately certified hospitals using a system governing body that is legally responsible for the conduct of two or more hospitals, the system governing body can elect to have unified and integrated infection prevention and control and antibiotic stewardship programs for all of its member hospitals after determining that such a decision is in accordance with all applicable State and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified hospitals meets all of the requirements of this section. Each separately certified hospital subject to the system governing body must demonstrate that:

(1) The unified and integrated infection prevention and control and antibiotic stewardship programs are established in a manner that takes into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital;

(2) The unified and integrated infection prevention and control and antibiotic stewardship programs establish and implement policies and procedures to ensure that the needs and concerns of each of its separately certified hospitals, regardless of practice or location, are given due consideration;

(3) The unified and integrated infection prevention and control and antibiotic stewardship programs have mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed; and

(4) A qualified individual (or individuals) with expertise in infection prevention and control and in antibiotic stewardship has been designated at the hospital as responsible for communicating with the unified infection prevention and control and antibiotic stewardship programs, for implementing and maintaining the policies and procedures governing infection prevention and control and antibiotic stewardship as directed by the unified infection prevention and control and antibiotic stewardship programs, and for providing education and training on the practical applications of infection prevention and control and antibiotic stewardship to hospital staff.

§ 482.43 Condition of participation: Discharge planning.

The hospital must have in effect a discharge planning process that applies to all patients. The hospital's policies and procedures must be specified in writing.

(a) *Standard: Identification of patients in need of discharge planning.* The hospital must identify at an early stage of hospitalization all patients who are likely to suffer adverse health consequences upon discharge if there is no adequate discharge planning.

(b) *Standard: Discharge planning evaluation.* (1) The hospital must provide a discharge planning evaluation to the patients identified in paragraph (a) of this section, and to other patients upon the patient's request, the request of a person acting on the patient's behalf, or the request of the physician.

(2) A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of, the evaluation.

(3) The discharge planning evaluation must include an evaluation of the likelihood of a patient needing post- hospital services and of the availability of the services.

(4) The discharge planning evaluation must include an evaluation of the likelihood of a patient's capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the hospital.

(5) The hospital personnel must complete the evaluation on a timely basis so that appropriate arrangements for post-hospital care are made before discharge, and to avoid unnecessary delays in discharge.

(6) The hospital must include the discharge planning evaluation in the patient's medical record for use in establishing an appropriate discharge plan and must discuss the results of the evaluation with the patient or individual acting on his or her behalf.

(c) *Standard: Discharge plan.* (1) A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of, a discharge plan if the discharge planning evaluation indicates a need for a discharge plan.

(2) In the absence of a finding by the hospital that a patient needs a discharge plan, the patient's physician may request a discharge plan. In such a case, the hospital must develop a discharge plan for the patient.

(3) The hospital must arrange for the initial implementation of the patient's discharge plan.

(4) The hospital must reassess the patient's discharge plan if there are factors that may affect continuing care needs or the appropriateness of the discharge plan.

(5) As needed, the patient and family members or interested persons must be counseled to prepare them for post-hospital care.

(6) The hospital must include in the discharge plan a list of HHAs or SNFs that are available to the patient, that are participating in the Medicare program, and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the case of a SNF, in the geographic area requested by the patient. HHAs must request to be listed by the hospital as available.

(i) This list must only be presented to patients for whom home health care or post-hospital extended care services are indicated and appropriate as determined by the discharge planning evaluation.

(ii) For patients enrolled in managed care organizations, the hospital must indicate the availability of home health and posthospital extended care services through individuals and entities that have a contract with the managed care organizations.

(iii) The hospital must document in the patient's medical record that the list was presented to the patient or to the individual acting on the patient's behalf.

(7) The hospital, as part of the discharge planning process, must inform the patient or the patient's family of their freedom to choose among participating Medicare providers of posthospital care services and must, when possible, respect patient and family preferences when they are expressed. The hospital must not specify or otherwise limit the qualified providers that are available to the patient.

(8) The discharge plan must identify any HHA or SNF to which the patient is referred in which the hospital has a disclosable financial interest, as specified by the Secretary, and any HHA or SNF that has a disclosable financial interest in a hospital under Medicare. Financial interests that are disclosable under Medicare are determined in accordance with the provisions of part 420, subpart C, of this chapter.

(d) *Standard: Transfer or referral.* The hospital must transfer or refer patients, along with necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed, for followup or ancillary care.

(e) *Standard: Reassessment.* The hospital must reassess its discharge planning process on an on-going basis. The reassessment must include a review of discharge plans to ensure that they are responsive to discharge needs.

[59 FR 64152, Dec. 13, 1994, as amended at 69 FR 49268, Aug. 11, 2004]

EFFECTIVE DATE NOTE: At 84 FR 51882, Sept. 30, 2019, § 482.43 was revised, effective Nov. 29, 2019. For the convenience of the user, the revised text is set forth as follows:

§ 482.43 Condition of participation: Discharge planning.

The hospital must have an effective discharge planning process that focuses on the patient's goals and treatment preferences and includes the patient and his or her caregivers/support person(s) as active partners in the discharge planning for post-discharge care. The discharge planning process and the discharge plan must be consistent with the patient's goals for care and his or her treatment preferences, ensure an effective transition of the patient from hospital to post-discharge care, and reduce the factors leading to preventable hospital readmissions.

(a) *Standard: Discharge planning process.* The hospital's discharge planning process must identify, at an early stage of hospitalization, those patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning and must provide a discharge planning evaluation for those patients so identified as well as for other patients upon the request of the patient, patient's representative, or patient's physician.

(1) Any discharge planning evaluation must be made on a timely basis to ensure that appropriate arrangements for post-hospital care will be made before discharge and to avoid unnecessary delays in discharge.

(2) A discharge planning evaluation must include an evaluation of a patient's likely need for appropriate post-hospital services, including, but not limited to, hospice care

services, post-hospital extended care services, home health services, and non-health care services and community based care providers, and must also include a determination of the availability of the appropriate services as well as of the patient's access to those services.

(3) The discharge planning evaluation must be included in the patient's medical record for use in establishing an appropriate discharge plan and the results of the evaluation must be discussed with the patient (or the patient's representative).

(4) Upon the request of a patient's physician, the hospital must arrange for the development and initial implementation of a discharge plan for the patient.

(5) Any discharge planning evaluation or discharge plan required under this paragraph must be developed by, or under the supervision of, a registered nurse, social worker, or other appropriately qualified personnel.

(6) The hospital's discharge planning process must require regular re-evaluation of the patient's condition to identify changes that require modification of the discharge plan. The discharge plan must be updated, as needed, to reflect these changes.

(7) The hospital must assess its discharge planning process on a regular basis. The assessment must include ongoing, periodic review of a representative sample of discharge plans, including those patients who were readmitted within 30 days of a previous admission, to ensure that the plans are responsive to patient post-discharge needs.

(8) The hospital must assist patients, their families, or the patient's representative in selecting a post-acute care provider by using and sharing data that includes, but is not limited to, HHA, SNF, IRF, or LTCH data on quality measures and data on resource use measures. The hospital must ensure that the post-acute care data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and treatment preferences.

(b) *Standard: Discharge of the patient and provision and transmission of the patient's necessary medical information.* The hospital must discharge the patient, and also transfer or refer the patient where applicable, along with all necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, at the time of discharge, to the appropriate post-acute care service providers and suppliers, facilities, agencies, and other outpatient service providers and practitioners responsible for the patient's follow-up or ancillary care.

(c) *Standard: Requirements related to post-acute care services.* For those patients discharged home and referred for HHA services, or for those patients transferred to a SNF for post-hospital extended care services, or transferred to an IRF or LTCH for specialized hospital services, the following requirements apply, in addition to those set out at paragraphs (a) and (b) of this section:

(1) The hospital must include in the discharge plan a list of HHAs, SNFs, IRFs, or LTCHs that are available to the patient, that are participating in the Medicare program, and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the case of a SNF, IRF, or LTCH, in the geographic area requested by the patient. HHAs must request to be listed by the hospital as available.

(i) This list must only be presented to patients for whom home health care post-hospital extended care services, SNF, IRF, or LTCH services are indicated and appropriate as determined by the discharge planning evaluation.

(ii) For patients enrolled in managed care organizations, the hospital must make the patient aware of the need to verify with their managed care organization which practitioners, providers or certified suppliers are in the managed care organization's network. If the hospital has information on which practitioners, providers or certified supplies are in the network of the patient's managed care organization, it must share this with the patient or the patient's representative.

(iii) The hospital must document in the patient's medical record that the list was presented to the patient or to the patient's representative.

(2) The hospital, as part of the discharge planning process, must inform the patient or the patient's representative of their freedom to choose among participating Medicare providers and suppliers of post-discharge services and must, when possible, respect the patient's or the patient's representative's goals of care and treatment preferences, as well as other preferences they express. The hospital must not specify or otherwise limit the qualified providers or suppliers that are available to the patient.

(3) The discharge plan must identify any HHA or SNF to which the patient is referred in which the hospital has a disclosable financial interest, as specified by the Secretary, and any HHA or SNF that has a disclosable financial interest in a hospital under Medicare. Financial interests that are disclosable under Medicare are determined in accordance with the provisions of part 420, subpart C, of this chapter.

§ 482.45 Condition of participation: Organ, tissue, and eye procurement.

(a) *Standard: Organ procurement responsibilities.* The hospital must have and implement written protocols that:

(1) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third

party designated by the OPO of individuals whose death is imminent or who have died in the hospital. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the hospital for this purpose;

(2) Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;

(3) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its options to donate organs, tissues, or eyes or to decline to donate. The individual designated by the hospital to initiate the request to the family must be an organ procurement representative or a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation;

(4) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;

(5) Ensure that the hospital works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.

(b) *Standard: Organ transplantation responsibilities.* (1) A hospital in which organ transplants are performed must be a member of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274) and abide by its rules. The term ''rules of the OPTN'' means those rules provided for in regulations issued by the Secretary in accordance with section 372 of the PHS Act which are enforceable under 42 CFR 121.10. No hospital is considered to be out of compliance with section 1138(a)(1)(B) of the Act, or with the requirements of this paragraph, unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the hospital from the OPTN and has notified the hospital in writing.

(2) For purposes of these standards, the term ''organ'' means a human kidney, liver, heart, lung, or pancreas.

(3) If a hospital performs any type of transplants, it must provide organ-transplant-related data, as requested by the OPTN, the Scientific Registry, and the OPOs. The hospital must also provide such data directly to the Department when requested by the Secretary.

[63 FR 33875, June 22, 1998]

Subpart D—Optional Hospital Services

§ 482.51 Condition of participation: Surgical services.

If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

(a) *Standard: Organization and staffing.* The organization of the surgical services must be appropriate to the scope of the services offered.

(1) The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.

(2) Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as ''scrub nurses'' under the supervision of a registered nurse.

(3) Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical